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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/996,977 | 11/20/2001 | Benjamin R. Willemstyn | | 4707 |

7590 10/25/2002

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EXAMINER

DEAK, LESLIE R

ART UNIT

PAPER NUMBER

3762

DATE MAILED: 10/25/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

| | | |
|-----------------|-------------------------|--|
| Application No. | Applicant(s) | |
| 09/996,977 | WILLEMSTYN, BENJAMIN R. | |
| Examiner | Art Unit | |
| Leslie R. Deak | 3762 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 November 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 November 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Drawings

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "3" has been used to designate two different structures in FIG 5. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.
2. The drawings are objected to under 37 CFR 1.83(a) because they fail to show cable tie 14 as described in the specification. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance,

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
4. Claims 5-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Art Unit: 3762

5. Claim 5 recites the limitation "the other end" in line 1. There is insufficient antecedent basis for this limitation in the claim. Further, it is unclear to which end applicant is referring.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

7. Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipated by US 6,200,300 to Petriekis et al. Petriekis discloses a container with a spout 24 with two ends with a flange portion 56 thereon. The flanged portion of the spout is heat sealed with the container to become integral with the container (column 4, lines 30-45).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 3-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,200,300 to Petriekis et al. Petriekis discloses a container with a spout 24 with two ends with a flange portion 56 thereon. The flanged portion of the spout is heat sealed with the container to become integral with the container (column 4, lines 30-45). With regard to the shape of the flange, It would have been an obvious matter of design choice to make the flange flat or curved, since such a modification would have involved a mere change in the form or shape of a component. A change in form or shape is generally recognized as being within the level of ordinary skill in the art. In re Dailey, 149 USPQ 47 (CCPA 1976). Furthermore, applicant fails to disclose any criticality of the shape of the flange, and the device appears to function equally well with a straight or curved flange.

10. Claims 2 and 7-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,200,300 to Petriekis et al in view of US 6,039,718 to Niedospial, Jr. et al. Petriekis discloses the apparatus as claimed with the exception of the second enclosure bag. Niedospial discloses a universal connector 30 which may be integral with the bag 10 (column 6, lines 55-58) and further comprises an overwrap 210. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to cover the bag with flanged connector disclosed by Petriekis with the overwrap disclosed by Niedospial in order to protect the bag and its contents, as taught by Niedospial.

With regard to applicant's limitation drawn to the location of the flange intermediate the ends of the connector, it would have been obvious to one of ordinary skill in the art at the time of invention to move the flange to a location between the ends

Art Unit: 3762

of the connector, since it has been held that rearranging the parts of an invention involves only routine skill in the art.

11. Claims 5-6, as best understood, are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,200,300 to Petriekis et al in view of US 3,006,341 to Poitras. Petriekis discloses the apparatus as claimed with the exception of a second fluid bag and an overwrap. Poitras discloses a bag 10 with a connector 17 that connects to a second fluid chamber 18 (see FIG 1). With regard to applicant's claim drawn to the size of the second chamber, it would have been an obvious matter of design choice to attach a larger second fluid chamber to the connector, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. In re Rose, 105 USPQ 237 (CCPA 1955). Furthermore, Poitras discloses a container 50 for packaging his entire apparatus (column 5, lines 13-40) such that the sterility of the package may be preserved (column 1, lines 66-70). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to combine the bag with the flanged connector disclosed by Petriekis with the secondary container and overwrap disclosed by Poitras in order to maintain a hermetically sealed, sterile fluid transfer system, as taught by Poitras.

12. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,200,300 to Petriekis et al in view of US 6,039,718 to Niedospial, Jr. et al., further in view of US 5,088,994 to Porat et al. The combined Petriekis and Niedospial device discloses the apparatus as claimed with the exception of the connector comprising a

Art Unit: 3762

hose barb device. However, Niedospial discloses that his connector is capable of connecting to other devices using means well-known in the art. Porat discloses a bag 1 with a connector spout 11 with a serrated outer surface. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to provide the connector with serrated or hose-barb edges in order to more securely connect the connector to any desired tubing, as taught by Porat.

13. Claims 14-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,200,300 to Petriekis et al in view of US 6,183,460 to Smith et al. Petriekis discloses a sealed pouch with a connector and a flange, but does not disclose a heat-sealed or zippered connection. Smith discloses a chamber 22 with outlet port 34 (column 4, lines 42-50). Smith further discloses flaps that provide an overwrap that may be sealed by a zip strip, weld seal, or a combination of both (column 6, lines 1-10). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to substitute the heat-sealed edges of the bag disclosed by Petriekis with the zipper closure and zipper-seal combination closure disclosed by Smith in order to provide a disengageable seal, as taught by Smith.

Conclusion

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

- a. US 2,838,046 Butler
- i. Container with flanged connector


Art Unit: 3762

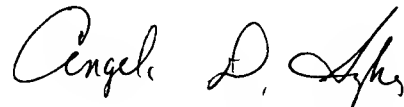
- b. US 4,523,679 Paikoff et al
 - ii. Pre-sterilized medical kit package
- c. US 4,657,540 Iwamoto et al
 - iii. Container with connector in a sterilized package
- d. US 5,391,163 Christine et al
 - iv. Container with connector and sterile overpouch

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 703-305-0200. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703-308-5181. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3590 for regular communications and 703-305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0873.

Ird/
October 17, 2002



ANGELA D. SYKES
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